

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/679,012

Confirmation No.: 8925

Applicant: Nicholas M. Cordaro

Filed: 10/03/03

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Examiner: Swiger III, James L.

Docket No.: SEA1-N35a

DECLARATION OF NICHOLAS M. CORDARO

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

I, Nicholas M. Cordaro, hereby declare as follows:

1. I am the inventor of the cervical plate/screw system described and claimed in the subject application and through this declaration request that the arguments, advanced in the final rejection dated December 28, 2006, judging the independent and many dependent claims unpatentable as being obvious over the cited art be reconsidered.
2. With respect to my qualifications for the statements made herein, I received a BS degree in Mechanical Engineering from New Mexico State University in 1997 and a Master's degree in Biomedical Engineering from the University of Arizona in 2000. I have worked as an orthopedic engineer since 2000 and as a spinal engineering specialist

since 2001, i.e., for Biomet Orthopedic (2000-2001), Alphatec Manufacturing (2001-2002) and my present employer and assignee of this application SeaSpine, Inc. (“SeaSpine”) from 2002 to date.

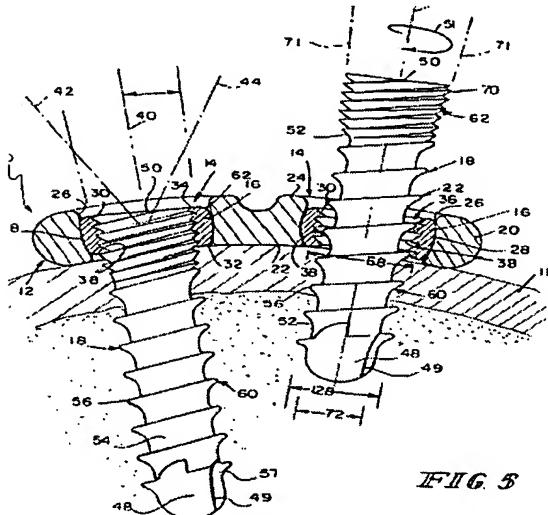
3. I am the sole or co-inventor of the additional orthopedic and related mechanisms described in the following publications:

| Publication No. | Title  | Pub. Date  |
|-----------------|--|------------|
| US20050197708A1 | Shoulder prosthesis  | 2005-09-08 |
| US20050107882A1 | Modular humeral head resurfacing system  | 2005-05-19 |
| US20050010222A1 | Transverse connector system  | 2005-01-13 |
| US20040153161A1 | Humeral stem with anatomical location of taper access for fixation of humeral head           | 2004-08-05 |
| US20040068319A1 | Cervical plate/screw system for immobilizing vertebral bodies                                | 2004-04-08 |
| US20030028253A1 | Shoulder prosthesis  | 2003-02-06 |
| US7160301       | Transverse connector system  | 2007-01-09 |
| WO06119092A3    | Motion restoring intervertebral device   | 2006-11-09 |
| WO06119092A2    | Motion restoring intervertebral device   | 2006-11-09 |
| WO06119088A2    | Prosthesis for restoring motion in an appendage or spinal joint and an intervertebral spacer | 2006-11-09 |
| US20060259038A1 | Transverse connector system  | 2006-11-16 |
| US6942699       | Shoulder prosthesis  | 2005-09-13 |
| US6783549       | Modular humeral head resurfacing system  | 2004-08-31 |

4. As is pointed out in the background of the invention section of the subject application, orthopedic plates are commonly used in conjunction with bone screws to align and maintain the alignment between adjacent vertebrae to accommodate a fusion process. To successfully accomplish the surgical procedure it is important that the plate be pulled flush against the vertebral bodies when the screws are fully inserted into the underlying bone. It is also important, and in fact critical, that the screws not be allowed to detach from the plate following surgery. Spinal movement and/or changes in the bone, in which the bone screw is embedded, apply forces to the screw, including forces along the longitudinal axis of the screw. Such forces, over time, may loosen the screw/plate connection unless counteracted, allowing the screw to be pushed out of the plate. A key feature of the present invention is the simplicity in which a screw and plate alone accomplish both objectives of allowing the plate to be pulled flush against the bone during surgery and subsequently holding the screw within the plate.

5. There have been many prior art attempts to position a bone screw within an orthopedic plate and prevent the bone screw from retracting from the plate once implanted as attested to by perhaps a hundred patents and published applications. This is referred to as "screw back out" within the spine literature. The patents and applications cited by or called to the attention of the Examiner include everything from blocking plates (or screws), as with the Lowery et al. US 5,364,399 patent ("399 patent"), to complex springs and sliders.

6. There are also devices consisting of bone screws which are threaded directly to the plate. See U.S. Patent Nos. 5,601,553 ("533 patent"), 5,954,722 ("722 patent"), and 6,129,730 ("730 patent"). Fig. 5 of the '722 patent is included below:



9. If my plate/system was obvious it would seem to me that the manufacturer of the '722 locking/plate screw system (DePuy Acromed) surely would have made the modifications, drastically improving their product. Instead, they chose to design entirely new cervical plates/screw systems and apparently discontinued marketing the '722 device (possibly known as the Peak Anterior Cervical Plate). Reference DePuy Spine, Inc. a Johnson & Johnson company (<http://www.onlinespinecenter.com/Default.aspx?tabid=87>)

*Current offerings: Anterior Cervical Offerings*

*DOC Rod*

*EAGLE™ Rigid Anterior Cervical Plate System*

*SKYLINE™ Anterior Cervical Plate System*

*SLIM LOC® Anterior Cervical Plate System*

*SWIFT™ Dynamic Anterior Cervical Plate System*

*UNIPLATE™ Anterior Cervical Plate System*

10. The Lowery et al. '399 patent, cited in the Office Action, discloses a device in which the screw is prevented from backing out of the plate by a secondary cap or locking screw (45) as shown below with respect to a commercial version of the '399 plate/screw system:



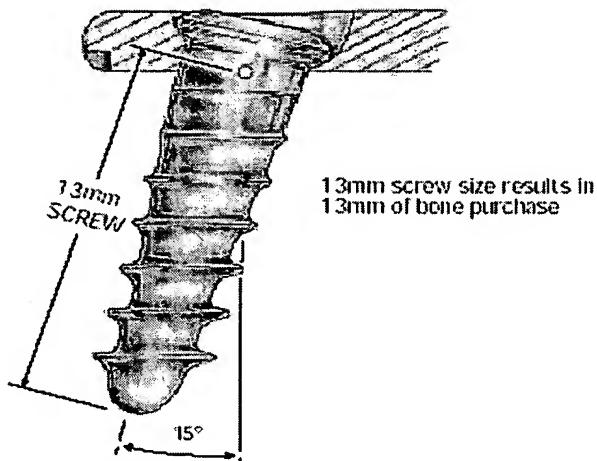
Orion

11. There is no back out prevention interface directly between the plate and screw implied or disclosed by the '399 patent.

12. The '399 patent is further described within the "Orion® Anterior Cervical Plate System Surgical Technique" by Gary L. Lowery (published by Medtronic Sofamor Danek).

13. The technique guide (confirming the patent disclosure) shows a detailed view of the neck of the screw as being of equal or greater than diameter of the major thread diameter as shown below:

**6C Determining Bone Screw Length**



14. There is nothing to prevent the bone screw from backing out without the secondary locking mechanism as is pointed out in the '399 patent, i.e., "locking screw 45 provides a means for rigidly fixing the bone engaging screws to the fixation plate." (Col. 7, lines 29-31) The statement in the Office Action that the screw of the '399 patent "may be fixated relative to the slot. . ." is not understood since the patent states that the "diagonal slot 50 preferably does not include any means for rigidly fixing the head of the screw to the plate." (8:1-3)

15. The second reference to Ralph, U.S. Patent No. 5,683,393 ("‘393 patent") was apparently applied only to those claims defining the plate opening as a slot. However, the plate 20 in the Lowery et al ‘399 patent is not threaded and the bone screw is prevented from backing out only by the secondary cap or locking screw shown in Fig. 5 (or O-ring 69 shown in Fig. 6). My invention eliminates the extra elements and the cost and time for assembling such elements. The ‘393 patent appears to have no relationship or relevance to either my invention (described in the subject application) or to the ‘399 patent.

16. The ‘393 patent is for a rod locking mechanism, is not for a plate and bone screw combination, and does not have any features that resemble a plate or screw device with a lag feature. A lag feature within the Ralph device would disallow the intended function of the device.

17. It should be noted that the ‘399 patent specifically points out that the bone screws "are highly restricted in their ability to wobble or rotate within the recess 20 of the bone screw bore when clamped by the locking screw." (7:31-34) This teaching would preclude the incorporation of a lag feature since there would be nothing between the screw and the plate to prevent the screw from rotating in a direction to possibly exit the plate, i.e., the screw would not be restricted in its ability to rotate. It is my belief (conformed by the Berry application discussed below at paragraph 0047) and backed up by experience in the field, that there is little tendency for a screw with the neck lag feature to rotate back out of the threaded plate. In any event, the ‘399 patent teaches away from the use of my simple neck lag feature.

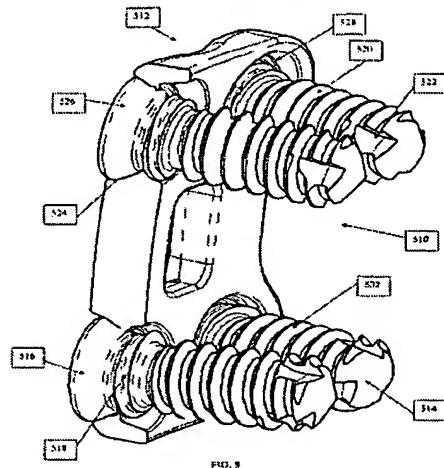
18. It seems to me that one interested in maintaining a bone screw in a plate, while eliminating the secondary locking cap of the '399 patent and it's ability to prevent screw counter-rotation, would look to the teachings of the '533, '722 and '730 patents, the shortcomings of which were discussed previously. To incorporate the male threads of the shaft 120 and the female threads of the hook element 102 of the '393 patent into the bone screw and plate of the '399 patent would seem to result in the plate/screw system of the '553, etc. patents. There would be no point in including the concave portions of the '393 male and female threads. The claim language that the screw can only be removed from the plate by reversing its rotation merely distinguishes the invention from the Lowery '393 system in which, absent the locking plate, the screw can be pushed out. Again, my invention is the simplicity of a plate/screw combination which allows the plate to be forced flush against the vertebral bodies during surgery and subsequently prevents the screw from being pushed out of the plate.

19. The third reference, Richelsoph et al, U.S. Patent No. 6,695,846 does include a plate and screw combination, but the back out feature relies solely on a sliding mechanism. This has no relevance to a threaded plate and threaded screw with a lag effect in my opinion. While I do not profess to be trained in patent law, as a spinal engineer, I do not believe that my invention as described and claimed in the subject application would have been obvious to a skilled artisan in view of the '399, '393 and '846 patents.

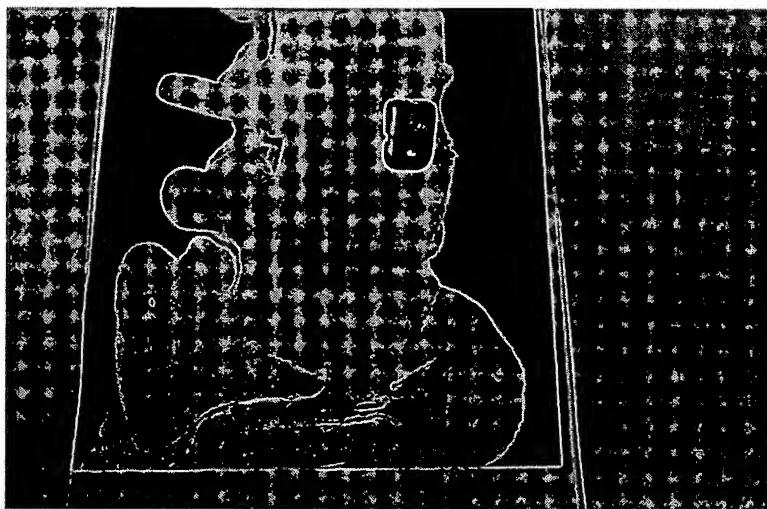
20. My unique and simplistic approach to preventing screw back out was recently "discovered" by Amedica Corporation ("Amedica"). This company has begun to market their ThreadLoc cervical plates based on pending U.S. application no. 20060276793A1

by Bret Berry, filed May 26, 2005. The inventor has done a nice job explaining why the simplicity of my invention is advantageous and unique; however, he appears to be unaware of my pending application or SeaSpine's commercial embodiment thereof. The Amedica device is shown below:

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21. Amedica obviously realizes the elegance of a simple helical thread cut within a plate while still allowing screw rotation to pull a plate flush with a vertebral body.
22. My invention, in the form of a buttress plate for preventing an implanted interbody spacer from extruding out of the spacer between separated intervertebral bodies, is shown below:



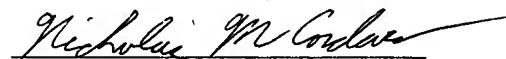
23. The buttress plate, placed on the market by SeaSpine approximately three years ago, has achieved considerable commercial success. During that time SeaSpine has been notified of only two instances in which the plate became dislodged. One instance was attributed to the degradation of the underlying bone and the other was attributed to, what I understand, was an implantation error.

24. I have forwarded commercial samples of the Orion plate/screw system as described in the '399 patent along with SeaSpine's buttress plate made in accordance with my invention to our counsel, Mr. Harold L. Jackson, and asked that, if possible, he submit such samples to the Examiner for his information.

25. For the above reasons I respectfully request that the basis for and the final rejection be reconsidered.

26. All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true, and further, that these statements made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent resulting therefrom.

Signed this 5<sup>th</sup> day of February, 2007 at Vista, California.



Nicholas M. Cordaro.